IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM Plaintiff, vs. ALNYLAM PHARMACEUTICALS INC. AND ALNYLAM U.S., INC. Defendants	Civil Action No. 1:24-cv-1524-DAE JURY TRIAL DEMANDED

PLAINTIFF'S MOTION TO STRIKE INEQUITABLE CONDUCT ALLEGATIONS

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I. INTRODUCTION

Defendants continue to mislead the Court. After having multiple meetings with MD Anderson, Defendants impermissibly took MD Anderson's breakthrough siRNA patented technology and built their drug business on the technology.[1] After being called to account for their infringement, Defendants have built their defense on false statements. For example, as an attempt to escape this venue, Defendants moved to transfer based on a declaration that falsely stated they do not require any of their employees to live here (they do). *Compare* Dkt. 21-1 at ¶ 10 (declaring that employees are not "required to live in the District") *with* Dkt. 25-1 at ¶ 9 (admitting that employees "are required to live in their respective territories" of Austin and San Antonio).

In a new attempt to escape liability, Defendants accuse Plaintiff and MD Anderson's leading cancer researchers of inequitable conduct—defrauding the Patent Office. And, like their motion to transfer, Defendants' inequitable conduct defense rests on a false allegation. Defendants claim that one of the inventors (Dr. Lopez-Berestein) concealed the contents of an international patent application from the Patent Office. That allegation is undisputedly false: Plaintiff disclosed the U.S. version of that international patent application, and the U.S. version contains the same relevant disclosure—word-for-word.

A basic investigation would have discovered that fact, which precludes Defendants' inequitable conduct defense as a matter of law. Defendants either did not conduct such an investigation or decided to lodge their inequitable defense allegations anyway. Rule 12(f) exists to strike these types of false and unsupported allegations of inequitable conduct—serious accusations that must comply with Rule 9(b)'s heightened pleading requirements. Defendants' Answer does

[1] Plaintiff in this case is The Board of Regents of the University System. MD Anderson is an institution that is part of the UT System.

not (and cannot) satisfy Rule 9(b). For these reasons, and those below, Plaintiff respectfully requests that the Court strike the entirety of Defendants' Third Defense – Inequitable Conduct (Dkt. 58 at 5–12) with prejudice.

II. APPLICABLE LAW

Because "the habit of charging inequitable conduct in almost every major patent case" had become "an absolute plague," courts now impose a high bar to plead and prove inequitable conduct. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc) (quotation and citation omitted). Patent challengers must plead inequitable conduct with specificity under Federal Rule of Civil Procedure 9(b) and provide the specific "who, what, when, where, and how" for each element. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009). Under *Therasense*, an inequitable conduct defense requires a showing by clear and convincing evidence of two separate elements: (1) the allegedly withheld or misrepresented information is material to patentability; and (2) the patentee acted with specific intent to mislead or deceive the PTO. 649 F.3d at 1291–92.

Because Defendants raised inequitable conduct as an affirmative defense (and not a counterclaim), Rule 12(f) provides a vehicle to dismiss those allegations. Federal Rule of Civil Procedure 12(f) authorizes a court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." "A Rule 12(f) motion to strike a defense is proper when the defense is insufficient as a matter of law." *Cabin Foods, LLC v. Rich Prods. Corp.*, No. EP-11-CV-318-KC, 2012 WL 433115, at *1–2 (W.D. Tex. Feb. 8, 2012). In general, "[a]ffirmative defenses must comply with the same pleading requirements as complaints." *Engineered Arresting Sys. Corp. v. Runway Safe LLC*, No. 1:15-CV-546-LY, 2016 WL 6087906, at *2 (W.D. Tex. Sept. 19, 2016). "A motion to strike may also be granted when a defense that is

subject to the heightened pleading standard of Rule 9(b)"—like inequitable conduct—"fails to meet Rule 9(b)'s requirements." *Cabin Foods*, 2012 WL 433115, at *1–2.

III. ARGUMENT

A. The Answer Fails to Allege Materiality Under Rule 9(b)

The Answer fails to adequately plead materiality under *Therasense* and should be stricken for three, independent reasons. First, Defendants' inequitable conduct defense hinges on allegations that are inadequately pleaded and undisputedly false. The Answer claims that Dr. Lopez-Berestein concealed the contents of an international patent application from the Patent Office. That allegation is demonstrably false. Second, the Answer fails to adequately allege that the inventor's (and Plaintiff's) statements to the Patent Office were misrepresentations: the statements expressly relate to siRNA (which is claimed), while the allegedly contrary evidence Defendants cite to does not relate to siRNA—and it ***was*** disclosed to the Patent Office. Third, the Answer fails to specify the basic "what," "why," and "how" that Rule 9(b) requires to plead materiality. For these reasons, Plaintiff respectfully requests that the Court strike the Answer's inequitable conduct allegations with prejudice.

1. A Central Allegation—That MD Anderson Withheld the Contents of the PCT Publication—Is Inadequately Pleaded and Undisputedly False

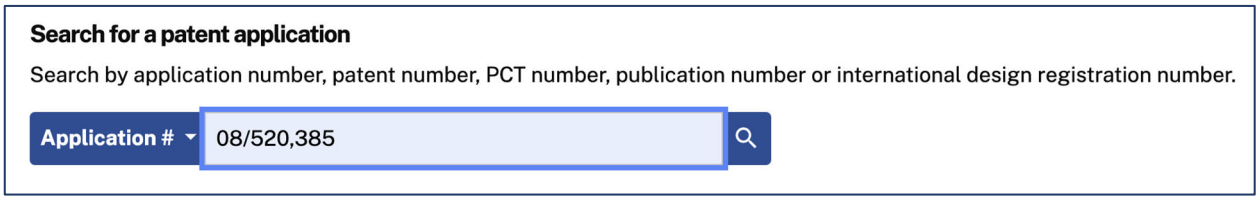
Defendants' inequitable conduct claim is based on the allegation that Dr. Lopez-Berestein concealed from the Patent Office the contents of an international patent application that lists him as the co-inventor, entitled "Liposomal Phosphodiester, Phosphorothioate, and p-Ethoxy Oligonucleotides" application (what the Answer calls the "PCT Publication"). Dkt. 58 at 9 (¶¶ 18–19); *id.* at 11 (¶ 26) (alleging materiality based on the "concealment of the PCT Publication and its contents"); *id.* at 12 (¶ 28) (alleging egregious misconduct based on failing to "bring[] to the Patent Office's attention the PCT Publication and/or its contents"). That allegation is false:

the PCT Publication's relevant disclosure was before the Patent Office during prosecution. Any basic diligence would have revealed that fact.

Plaintiff disclosed the U.S. version of the PCT Publication to the Patent Office during prosecution of the '717 Patent, and did so in 2009—before any alleged contradictory statements in Dr. Lopez-Berestein's 2010 declaration were made. As Defendants' Answer states, the PCT Publication "claims priority to U.S. Provisional Application 08/52,385." Dkt. 58 at 9 (¶ 19).

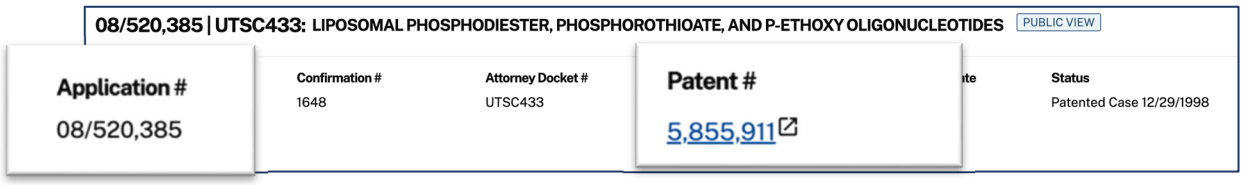
> 19. More specifically, Dr. Lopez-Berestein and Ana M. Tari are listed as authors on a 1997 publication under the Patent Cooperation Treaty ("PCT") titled "Liposomal Phosphodiester, Phosphorothioate, and p-Ethoxy Oligonucleotides," International Publication Number WO 97/07784 (hereinafter "PCT Publication"). This PCT Publication has an international publication date of March 6, 1997, well before Dr. Lopez-Berestein submitted his Declaration to the PTO. Ex. E. The PCT Publication claims priority to U.S. Provisional Application 08/520,385, filed on August 29, 1995. Dr. Lopez-Berestein signed a declaration on December 7, 1995, stating that the

A search of the Patent Office records[2] with that application number shows that the same application issued as a U.S. Patent—U.S. Patent No. 5,855,911 ("the '911 Patent").[3]



[2] https://patentcenter.uspto.gov/.

[3] Similarly, pulling up the PCT Publication on Google Patents would have revealed that it had a U.S. counterpart patent, the '911 Patent. *See, e.g.*, https://patents.google.com/patent/WO1997007784A2/ (hyperlink under "Worldwide applications" to the '911 Patent). The '911 Patent also lists the application as 520,385. Ex. 1 at (21).



The Patent-in-Suit (the '717 Patent) lists the '911 Patent as one of the References Cited during prosecution of the '717 Patent (Dkt. 1-1) at (56) (cropped and truncated).

References Cited

U.S. PATENT DOCUMENTS

5,811,119	A	9/1998	Mehta et al.	424/450
5,830,498	A	11/1998	Lenk et al.	424/450
5,855,911	A	1/1999	Lopez-Berestein et al.	424/450
5,962,016	A	10/1999	Willis	424/450

The record before the Patent Office shows that Plaintiff disclosed the '911 Patent to the Patent Office during prosecution of the application that issued as the '717 Patent. Ex. 2 (May 12, 2009 Information Disclosure Statement). Plaintiff disclosed the '911 Patent in 2009, before Dr. Lopez-Berestein's declaration in 2010.

Because the PCT Publication and the '911 Patent issued from the same patent application, they should have the same relevant disclosure. And a side-by-side comparison confirms that is the case: the portions of the PCT Publication that the Answer cites and '911 Patent are identical.

PCT Publication (Allegedly "Concealed")	**'911 Patent (Undisputedly Disclosed)**
The cellular uptake of antisense oligonucleotides is low. To solve this problem, physical techniques such as calcium-phosphate precipitation, DEAE-dextran mediation, or electroporation have been used to increase the cellular uptake of oligonucleotides. These techniques are difficult to reproduce and are inapplicable in vivo. Cationic lipids, such as Lipofectin, have also been used to deliver phosphodiester or phosphorothioate oligonucleotides. An	The cellular uptake of antisense oligonucleotides is low. To solve this problem, physical techniques such as calcium-phosphate precipitation, DEAE-dextran mediation, or electroporation have been used to increase the cellular uptake of oligonucleotides. These techniques are difficult to reproduce and are inapplicable in vivo. Cationic lipids, such as Lipofectin, have also been used to deliver phosphodiester or phosphorothioate oligonucleotides. An

PCT Publication (Allegedly "Concealed")	'911 Patent (Undisputedly Disclosed)
electrostatic interaction is formed between the cationic lipids and the negatively charged phosphodiester or phosphorothioate oligonucleotides, which results in a complex that is then taken up by the target cells. Since these cationic lipids do not protect the oligonucleotides from nuclease digestion, they are only useful in delivering the nuclease-resistant phosphorothioates, but not the nuclease-cleavable phosphodiesters. Another modified phosphodiester (PD) analog that has been prepared is p-ethoxy (pE) oligos. The modifications of pE oligos are made in the phosphate backbone so that the modification will not interfere with the binding of these oligos to the target mRNA. pE oligos are made by adding an ethyl group to the nonbridging oxygen atom of the phosphate backbone, thus rendering these oligos uncharged compounds. In spite of their resistance to nucleases, the cellular uptake and intracellular delivery of pE oligos are still poor because upon internalization, these oligos remain sequestered inside the endosomal/lysosomal vacuoles, impeding their access to the target mRNA. Dkt. 58-5 at 2:3–22 (cited at Dkt. 58 at 9–10).	electrostatic interaction is formed between the cationic lipids and the negatively charged phosphodiester or phosphorothioate oligonucleotides, which results in a complex that is then taken up by the target cells. Since these cationic lipids do not protect the oligonucleotides from nuclease digestion, they are only useful in delivering the nuclease-resistant phosphorothioates, but not the nuclease-cleavable phosphodiesters. Another modified phosphodiester (PD) analog that has been prepared is p-ethoxy (pE) oligos. The modifications of pE oligos are made in the phosphate backbone so that the modification will not interfere with the binding of these oligos to the target mRNA. pE oligos are made by adding an ethyl group to the nonbridging oxygen atom of the phosphate backbone, thus rendering these oligos uncharged compounds. In spite of their resistance to nucleases, the cellular uptake and intracellular delivery of pE oligos are still poor because upon internalization, these oligos remain sequestered inside the endosomal/lysosomal vacuoles, impeding their access to the target mRNA. Ex. 1 ('911 Patent) at 1:32–60.
The composition includes (a) a liposome which consists essentially of neutral phospholipids, and (b) an antisense oligonucleotide that is entrapped in the liposome and is selected from the group consisting of phosphodiester oligonucleotides, phosphorothioate oligonucleotides, and p-ethoxy oligonucleotides. The phospholipids are preferably phosphatidylcholines. An especially preferred phospholipid is dioleoylphosphatidyl choline. When the antisense oligonucleotide is a phosphodiester oligonucleotide, the preferred molar ratio of phospholipid to oligo is less than about 3,000:1. When the antisense oligonucleotide is	The composition includes (a) a liposome which consists essentially of neutral phospholipids, and (b) an antisense oligonucleotide that is entrapped in the liposome and is selected from the group consisting of phosphodiester oligonucleotides, phosphorothioate oligonucleotides, and p-ethoxy oligonucleotides. The phospholipids are preferably phosphatidylcholines. An especially preferred phospholipid is dioleoylphosphatidyl choline. When the antisense oligonucleotide is a phosphodiester oligonucleotide, the preferred molar ratio of phospholipid to oligo is less than about 3,000:1. When the antisense oligonucleotide is

<table>
<tr><th>PCT Publication (Allegedly “Concealed”)</th><th>’911 Patent (Undisputedly Disclosed)</th></tr>
<tr><td>a phosphorothioate oligonucleotide, the preferred molar ratio of phospholipid to oligo is between about 10:1 and about 50:1. When the antisense oligonucleotide is a p-ethoxy oligonucleotide, the preferred molar ratio of phospholipid to oligo is between about 5:1 and about 100:1.

Dkt. 58-5 at 2:26–3:10 (cited at Dkt. 58 at 10).</td><td>a phosphorothioate oligonucleotide, the preferred molar ratio of phospholipid to oligo is between about 10:1 and about 50:1. When the antisense oligonucleotide is a p-ethoxy oligonucleotide, the preferred molar ratio of phospholipid to oligo is between about 5:1 and about 100:1.

Ex. 1 (’911 Patent) at 1:67–2:16.</td></tr>
<tr><td><u>Development of liposomal-phosphorothioates</u> Similar incorporation protocol was used with phosphorothioates (PT) since PT and PD are structural analogs. Various molar ratios of DOPC to PT were used (Table 4). The effect of sonication of the liposomal mixture (before dialysis) was also studied. Table 4 Effect of lipid to oligonucleotide molar ratios on the incorporation of PT into liposomes. | Molar ratio	% incorporation without sonication	with sonication
10/1	>90	>90
50/1	>90	>90
100/1	45.8	55.5
200/1	44.1	49.1
500/1	27.8	47.0
1000/1	25.1	42.1 | Dkt. 58-5 at 10:7–14 (reproduced at Dkt. 58 at 10).</td><td>Development of liposomal-phosphorothioates Similar incorporation protocol was used with phosphorothioates (PT) since PT and PD are structural analogs. Various molar ratios of DOPC to PT were used (Table 4). The effect of sonication of the liposomal mixture (before dialysis) was also studied. TABLE 4 Effect of lipid to oligonucleotide molar ratios on the incorporation of PT into liposomes. | Molar ration	% incorporation without sonication	with sonication
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500/1	27.8	47.0
1000/1	25.1	42.1 | Ex. 1 (’911 Patent) at 6:1–9.</td></tr>
</table>

The PCT Publication thus cannot be material as a matter of law. *Star Sci., Inc. v. RJ Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008) (explaining that it is “well-established” that information is “not material if it is cumulative of other information already disclosed to the PTO”) (collecting authority); *Therasense*, 649 F.3d at 1292 (“A reference is not but-for material, however, if it is merely cumulative to, or less relevant than, information already considered by the examiner.”).

This is something Defendants knew or should have known before pleading inequitable

conduct, the '"atomic bomb' of patent law." *Therasense*, 649 F.3d at 1288. Indeed, one requirement to plead materiality—which is absent from the Answer—is to allege that the withheld information is not cumulative of other information that before the Patent Office. *Exergen*, 575 F.3d at 1329 (requiring pleading to identify what in the withheld reference was "supposedly absent from the information of record"); *Nalco Co. v. Turner Designs, Inc.*, No. 13-CV-02727 NC, 2014 WL 645365, at *5 (N.D. Cal. Feb. 19, 2014) (finding proposed pleading insufficient under Rule 9(b) where the pleading lacked facts showing that the withheld reference "was not cumulative of other references before the PTO"). The Answer's failure to include this allegation—which Defendants cannot make—warrants striking the defense with prejudice.

Defendants either did not conduct basic diligence before filing their Answer or were aware that the substance of the PCT Publication was before the Patent Office—and still accused Dr. Lopez-Berestein and MD Anderson of defrauding the Patent Office anyway. In either case, Defendants' defense fails as a matter of law and should be struck under Rule 12(f) with prejudice.

2. The Answer Fails to Plead an Affirmative Misrepresentation

The Answer also fails to adequately plead inequitable conduct based on the statements in Dr. Lopez-Berestein's Declaration,[4] Plaintiff's submissions to the Patent Office, or statements in the '717 Patent specification. Dkt. 58 at 6–12 (¶¶ 6–28). The Answer does not identify why those statements were material to patentability or how the Patent Office used those statements in view of the record before the Patent Office. For the Declaration, the Answer does not specify what statements are "unmistakenly false" or the "why" and " how" required to make out a claim of

[4] The Answer refers to a declaration from November 9, 2010 (Dkt. 58 at 7 (¶ 8)), but the exhibit is a declaration from 2014. Dkt. 58-4. Defendants also misspell Dr. Lopez-Berestein's name five times in their Answer. Dkt. 58 at 11 (¶¶ 24–26) (referring to "Dr. Lopez-Berenstein") (emphasis added).

egregious misconduct. Dkt. 58 at 11–12 (¶¶ 27–28). Likewise, all of the inequitable conduct allegations rest on the claim that the PCT Publication's substance was not before the Patent Office (*e.g.*, *id.* at ¶¶ 26, 28)—an accusation that is undisputedly false.

A review of the Answer also shows that Defendants fail to adequately plead that Plaintiff's and Dr. Lopez-Berestein's statements were affirmative misrepresentations. Every statement the Answer points to relates to siRNA (which the '717 Patent claims):

- "During the course of prosecuting the '639 Application, Plaintiff made repeated, exaggerated claims that the alleged inventors' use of a neutral liposome to encapsulate negatively charged nucleotides was novel and unexpected. Applicants referred to 'the central dogma regarding the use of cationic lipids to deliver siRNA,' and asserted that their discovery was 'surprising and unexpected.'" Dkt. 58 at 6–7 (¶ 6) (emphasis added) (citations omitted).

- "Plaintiff repeatedly emphasized this supposedly novel aspect of the invention in the specification as well, stating that 'the inventors have discovered that non-charged liposomes may be efficiently used to deliver an inhibitory nucleic acid such as siNA or siRNA,' and falsely alleging that prior work taught away from the idea that neutral liposomes would be effective." Dkt. 58 at 7 (¶ 7) (emphasis added) (citations omitted).

- "Plaintiff's response advanced the Declaration to argue that 'one of skill in the art at the time of the present invention' would understand 'that in the case of siRNA, a cationic liposome should be employed, hence teaching away from the present invention.'" Dkt. 58 at 8 (¶ 11) (emphasis added) (citations omitted).

- "The Declaration summarized and presented studies to demonstrate that 'the general understanding in the liposome field at a time just prior to the filing of our application was a cationic liposome was required to deliver nucleic acids, including siRNAs.'" Dkt. 58 at 8 (¶ 12) (emphasis added) (citations omitted).

- "The Declaration relied on these articles to support the argument that 'the general understanding in the literature prior to our application, in direct contrast to our invention, was that in the case of siRNA, the use of a positively charged lipid was critical.' The Declaration also argued that 'in the case of siRNA our data shows that a negatively charged backbone and a neutral liposome is needed to obtain a 90% encapsulation efficiency,' thereby suggesting that the claimed neutral liposome was the reason for the better performance than the prior art cationic liposomes." Dkt. 58 at 8–9 (¶ 16) (emphases added) (citations omitted).

- "The Declaration was submitted to the USPTO in support of the non-obviousness of the invention, during the prosecution of the '639 Application, with Plaintiff reiterating that 'the general understanding in the literature prior to our application, in direct contrast to our

> invention, was that in the case of siRNA, the use of a positively charged lipid was critical.'" Dkt. 58 at 9 (¶ 17) (emphases added) (citations omitted).

The only evidence the Answer identifies to allege that these statements were misrepresentations is the PCT Publication. Dkt. 58 at 9–11 (¶¶ 18–23). But the PCT Publication does not address siRNA—and the Answer does not allege that it does. The Answer instead points to the PCT Publication's disclosure that ASOs—not SiRNA—could be therapeutically delivered with neutral liposomes. Dkt. 58 at 9–10 (¶¶ 19-22).

ASOs and siRNA are not the same thing. The '717 Patent itself—in passages the Answer cites (Dkt. 58 at 7, 11 (¶¶ 7, 26))—expressly distinguishes ASOs from siRNA: it acknowledges that "[n]eutral liposomes were used to deliver therapeutic antisense oligonucleotides [ASOs]" in the prior art but states that it was "not clear if or to what degree neutral liposomes may be used to deliver siRNA." Dkt. 1-1 ('717 Patent) at 2:7–10. There are no statements about siRNA that the PCT Publication facially contradicts—the term "siRNA" is not even in the PCT Publication. Nor does the Answer allege that the PCT Publication (whose substance was before the Patent Office during prosecution) anticipated or rendered obvious the '717 Patent claims. And, critically, the Answer fails to explain why or how statements about ASOs shows that statements about siRNA are false, as Rule 9(b) requires. The egregious-misconduct standard requires pleading with specificity that the declaration was "unmistakably false." *Therasense*, 649 F.3d at 1292–93 (emphasis added); Dkt. 58 at 28 (alleging "egregious misconduct of filing an unmistakably false Declaration"). The Answer does not plead any facts to make that showing—teachings about ASOs do not make statements about siRNA false, just as teachings about an F-150 do not show that statements about a Chevy Silverado are false. Because the Answer does not (and cannot) make out an inequitable conduct case based on alleged misrepresentations, Plaintiff requests that the Court strike the inequitable conduct allegations with prejudice.

3. Defendants Pleading Lacks Key Elements to Allege Materiality

In addition to the above failings, the Answer fails to plead numerous aspects of materiality required under Rule 9(b). That Rule requires pleading the "what," "why," and "how" for materiality. For but-for materiality—which requires showing "that the PTO would not have allowed the claim but for the nondisclosure or misrepresentation," *In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 519 (Fed. Cir. 2012) (citing *Therasense*, 649 F.3d at 1287)—the Answer contains a single sentence: "Dr. Lopez-Berenstein's [sic] consistent misrepresentations, in both his Declaration and throughout the specification, and their persistent citation by applicants, including Dr. Lopez-Berenstein [sic], in support of the '639 Application over the obviousness rejection (along with his concealment of the PCT Publication and its contents) were material under the 'but for' materiality standard to the PTO's decision to ultimately issue the '639 Application as U.S. Patent No. 8.895,717." Dkt. 58 at 11 (¶ 26). This is insufficient.

The Answer does not, as the law requires, "identify which claims, and which limitations in those claims" the information pertains to (the "what") or "identify the particular claim limitations, or combination of claim limitations" that the information was material to compared to what information was before the Patent Office (part of the "why" and "how"). *Exergen*, 575 F.3d at 1329–30; *see also Cabin Foods*, 2012 WL 433115 (granting motion to strike where, among other deficiencies, the answer failed to alleged that the material information had "relevance to any specific claims or claim limitations" and failed to plead "facts sufficient to show why the alleged misstatements or omission were material and how the examiner would have used the information in assessing the patentability of the claims"); *Front Row Techs., LLC v. NBA Media Ventures, LLC*, 163 F. Supp. 3d 938, 986 (D.N.M. 2016) ("If the parties alleging inequitable conduct fail to cite specific claims in specific patents 'that would be deemed unpatentable in light of undisclosed information,' they have failed to allege materiality.") (citation omitted). And the Answer's single

sentence on materiality does not even identify with specificity "what" information Dr. Lopez-Berestein supposedly withheld or misrepresented during prosecution that meets *Therasense*'s materiality standard. Indeed, the Answer does not even identify any specific ground or prior art that Defendants allege would have invalidated the '717 Patent claims, reinforcing that its "but for" materiality allegations fail. Dkt. 58 at 5 (reciting only that "[o]ne or more claims of the asserted '717 Patent are invalid for failure to satisfy the conditions of patentability in 35 U.S.C. §§ 101 et seq., including, but not limited to §§ 101, 102, 103, and/or 112" but failing to identify any prior art references or theories). And the Answer fails to allege that the information allegedly withheld was not cumulative of information that was before the Patent Office during prosecution.

Defendants' egregious misconduct allegations similarly fail. The Answer only alleges the following: "In view of the PCT Publication discussed above and/or its contents, the Declaration is clearly a 'false affidavit'" because the declaration "contained knowingly false information about the status of the prior art and Dr. Lopez-Berestein's own published work without bringing to the Patent Office's attention the PCT Publication and/or its contents as discussed above." Dkt. 58 at 12 (¶ 28). But this allegation is undisputedly false: the PCT Publication's contents were disclosed to the Patent Office. And the allegation does not specify the "what," "why," and "how" surrounding the allegedly "false information." The Answer only points to the PCT Publication's disclosure, which on its face does not contain evidence of a false statement. This is insufficient to plead an inequitable conduct claim under Rule 9(b).

B. Defendants Fail to Plausibly Allege Intent to Deceive the Patent Office

In addition to failing to adequately allege materiality, the Answer also fails to satisfy Rule 9(b) regarding intent to deceive. On intent, the Answer only includes the following paragraphs.

- "Since Dr. Lopez-Berenstein [sic] was aware that negatively charged oligonucleotides could be encapsulated in neutral liposomes as of 1997, his statements in his Declaration submitted to the USPTO in 2010 that a person of skill in the art prior to the publication of

the ’639 Application would only have considered cationic liposomes for the encapsulation of siRNA (a negatively charged oligonucleotide) in 2007 constitute a knowing misrepresentation. The single most reasonable inference to be drawn from these facts is that Dr. Lopez-Berenstein’s [sic] conduct was the result of a specific intent to deceive USPTO.” Dkt. 58 at 11 (¶ 24).

- “The Declaration contained knowingly false information about the status of the prior art and Dr. Lopez-Berestein’s own published work without bringing to the Patent Office’s attention the PCT Publication and/or its contents as discussed above. Dr. Lopez-Berestein signed the Declaration under penalties of perjury and provided it to the USPTO, despite knowing it contained false information.” Dkt. 58 at 12 (¶ 28).

These allegations do not contain any specific allegations regarding Dr. Lopez-Berestein’s intent and thus fail to satisfy Rule 9(b). Defendants instead infer intent based on (1) the undisputedly false allegation that Dr. Lopez-Berestein did not disclose the substance of the PCT Publication to the Patent Office and (2) the conclusory allegation that Dr. Lopez-Beresetin’s declaration is false in view of the PCT Publication—which the PCT Publication itself does not support. Plaintiff (and Dr. Lopez-Berestein) disclosed the substance of the PCT Publication in 2009, before Dr. Lopez-Berestein’s declaration. And the ’717 Patent itself conclusively shows no intent to deceive: the Patent acknowledges that “[n]eutral liposomes were used to deliver therapeutic antisense oligonucleotides [ASOs]” in the prior art but states it was “not clear if or to what degree neutral liposomes may be used to deliver siRNA.” Dkt. 1-1 (’717 Patent) at 2:7–10. Defendants thus cannot plead intent to deceive under Rule 9(b) and the Court should strike Defendants’ inequitable conduct allegations with prejudice.

IV. CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Court grant this Motion to Strike and Court strike the entirety of Defendants’ Third Defense – Inequitable Conduct (Dkt. 58 at 5–12) with prejudice.

Dated: August 27, 2025

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing document has been served on all counsel of record via the Court's ECF system on August 27, 2025.

/s/ *Christian Hurt*
Christian Hurt